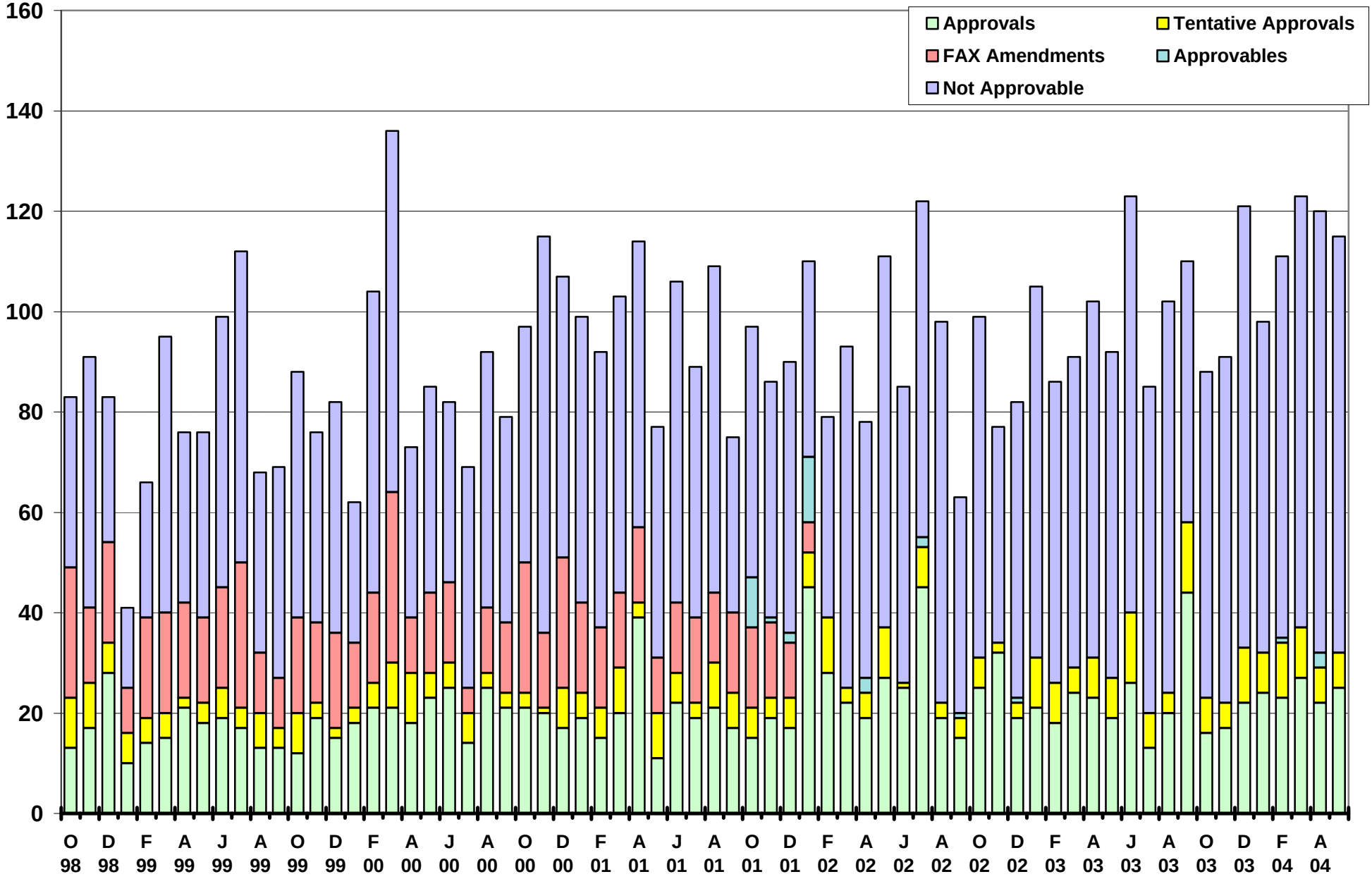
Center for Drug Evaluation and Research

Office of Generic Drugs

Monthly Quantitative Report
and Statistical Charts
May 2004

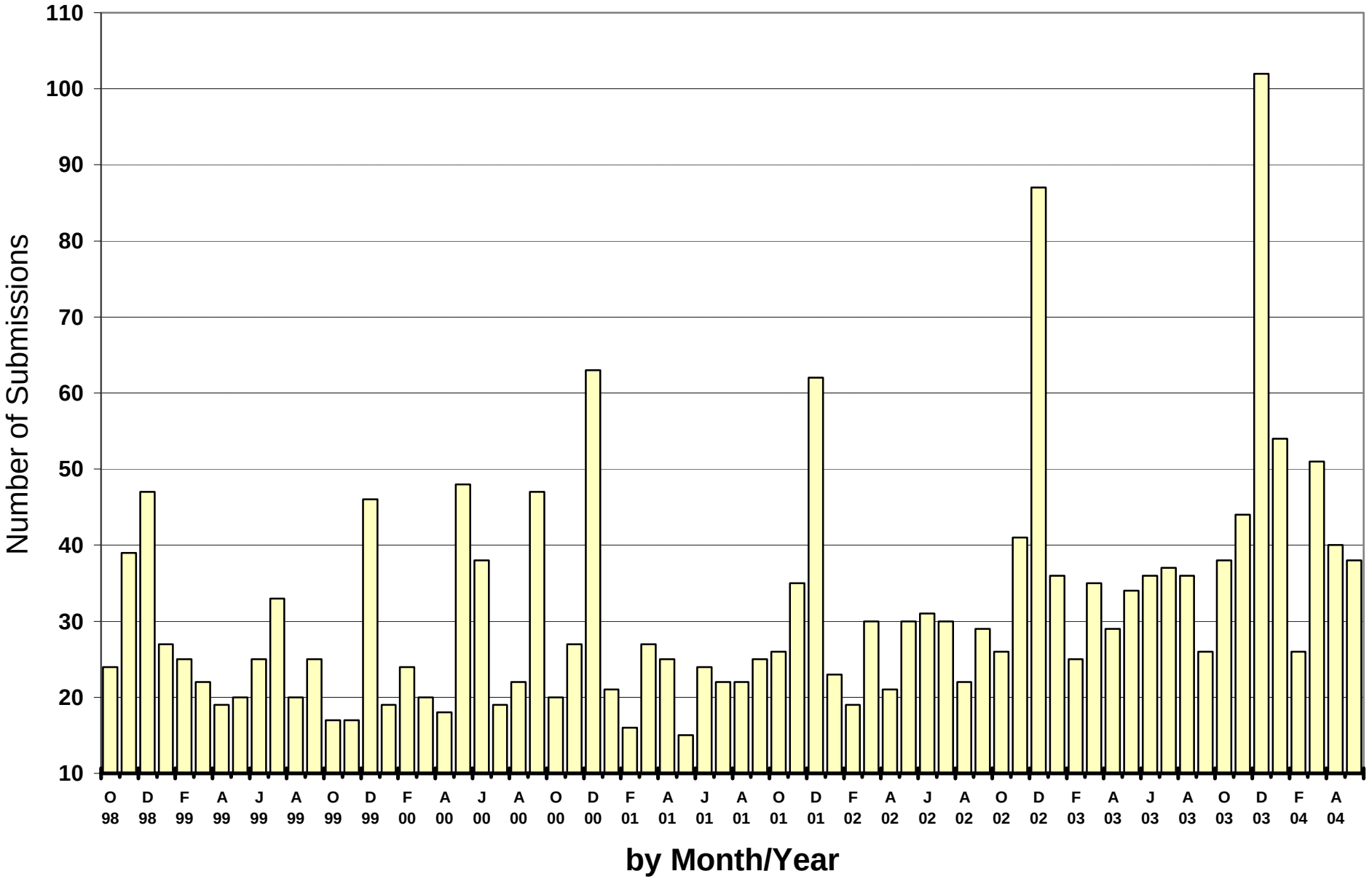
Actions on Original ANDAs



Note: Tentative Approvals (TA) are applications that have been approved by the office pending patent expiration. TAs and Approvables(AE) are counted as approvals subsequently when approved.

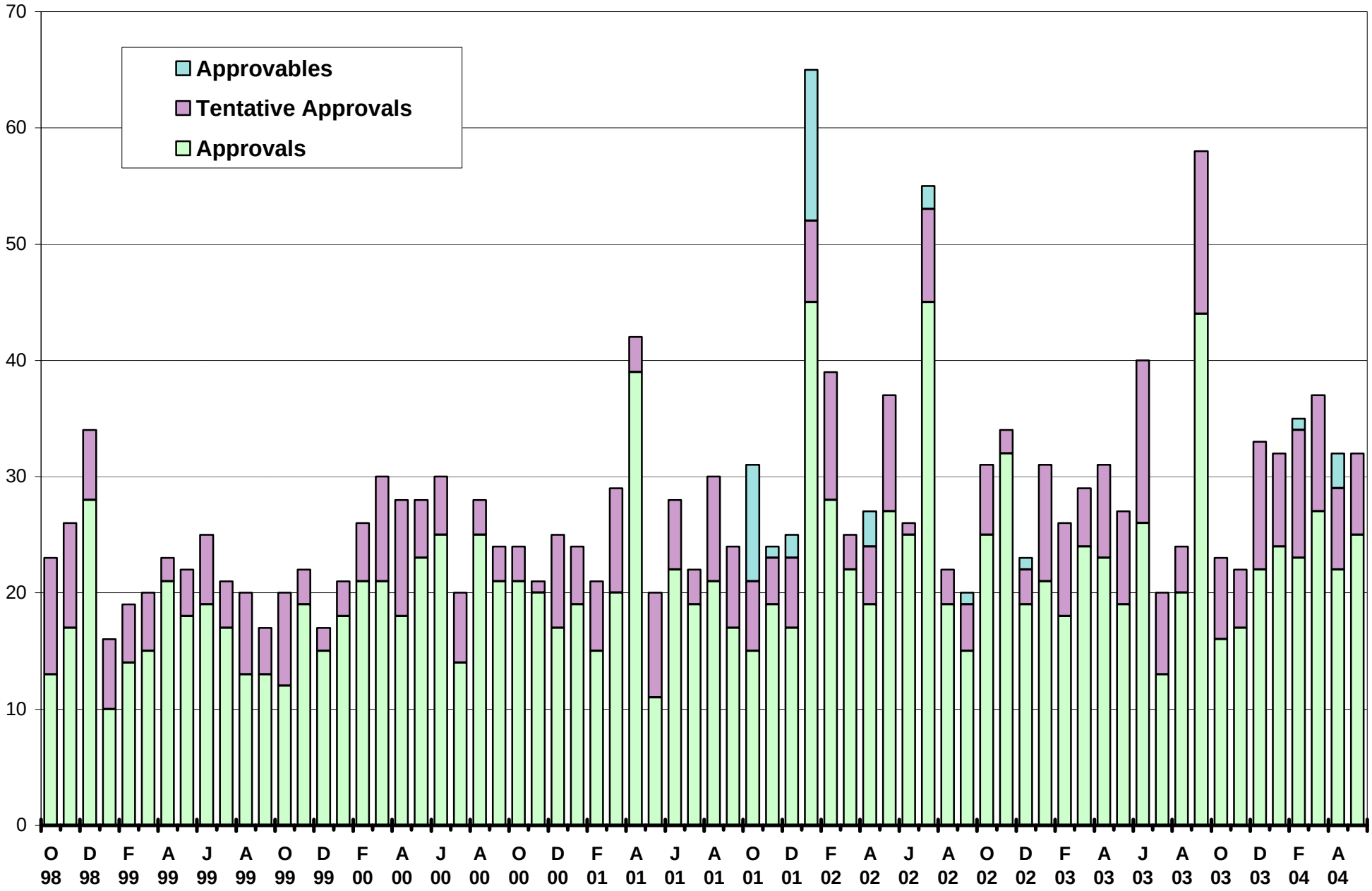
May 2004

Original ANDAs Received



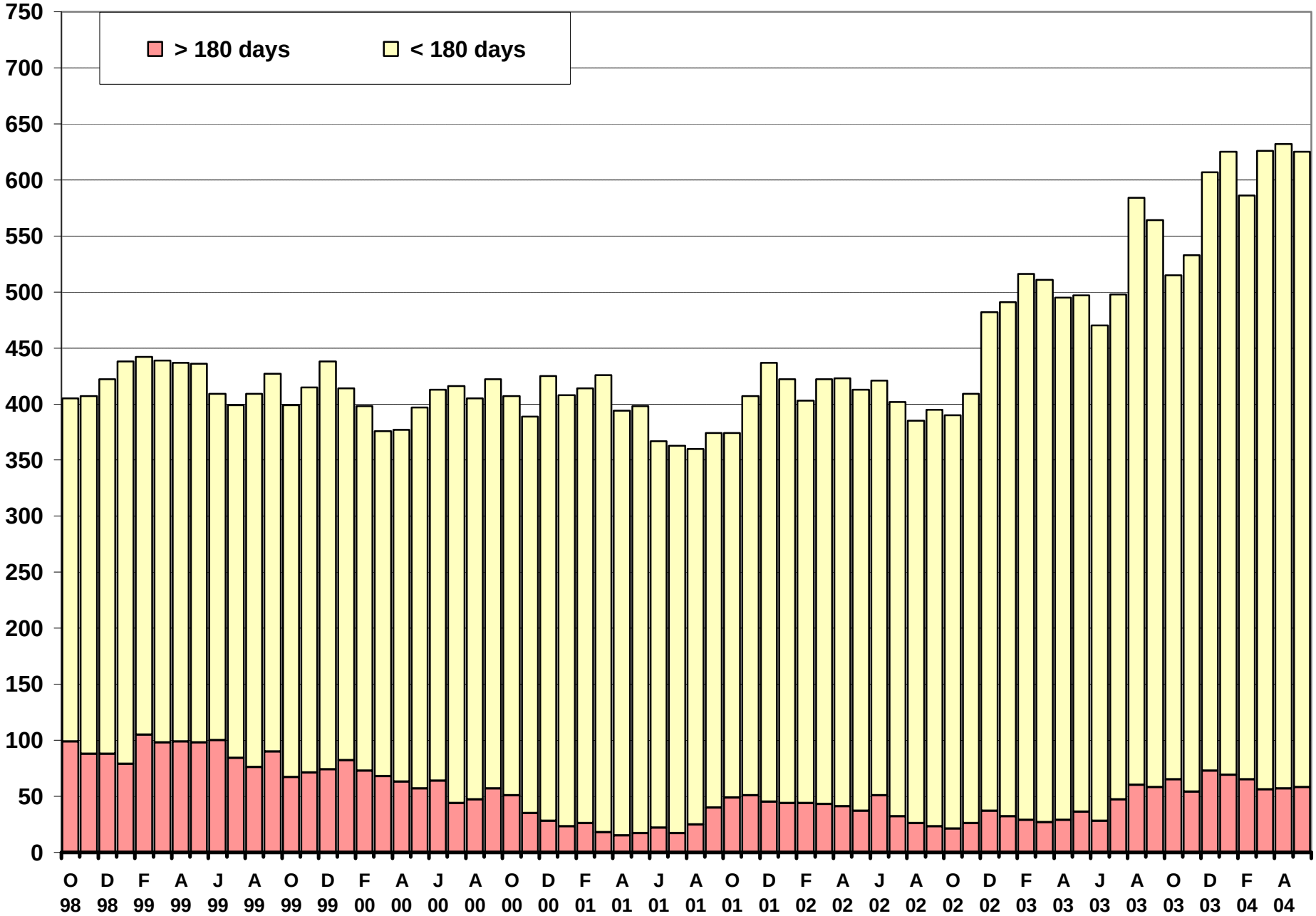
May 2004

Original ANDAs Approved or Tentatively Approved

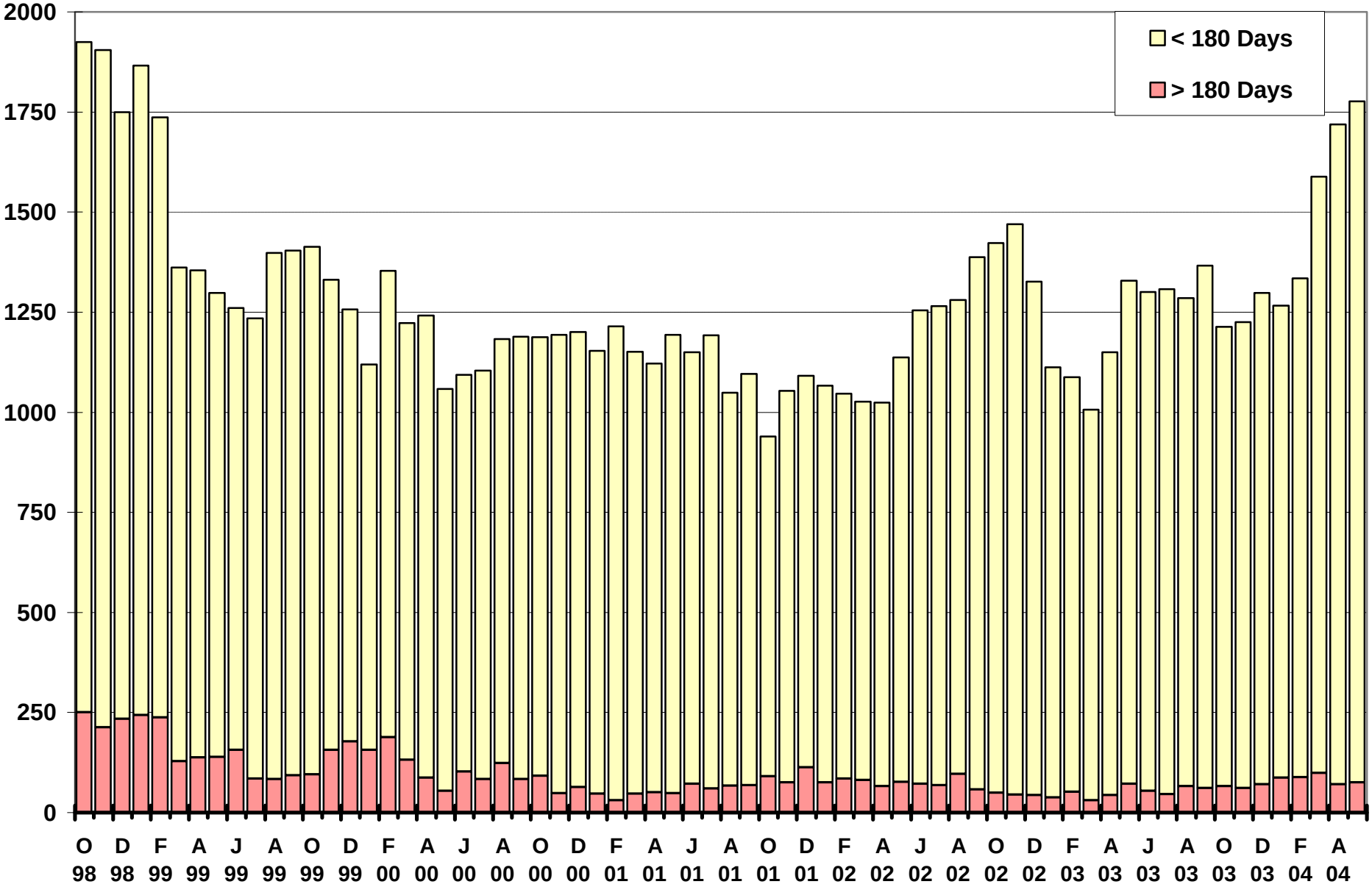


Note: Tentative Approvals (TA) are applications that have been approved by the office pending patent expiration. TAs and Approvables (AE) are counted as approvals subsequently when approved.

Original ANDAs Pending Per Month

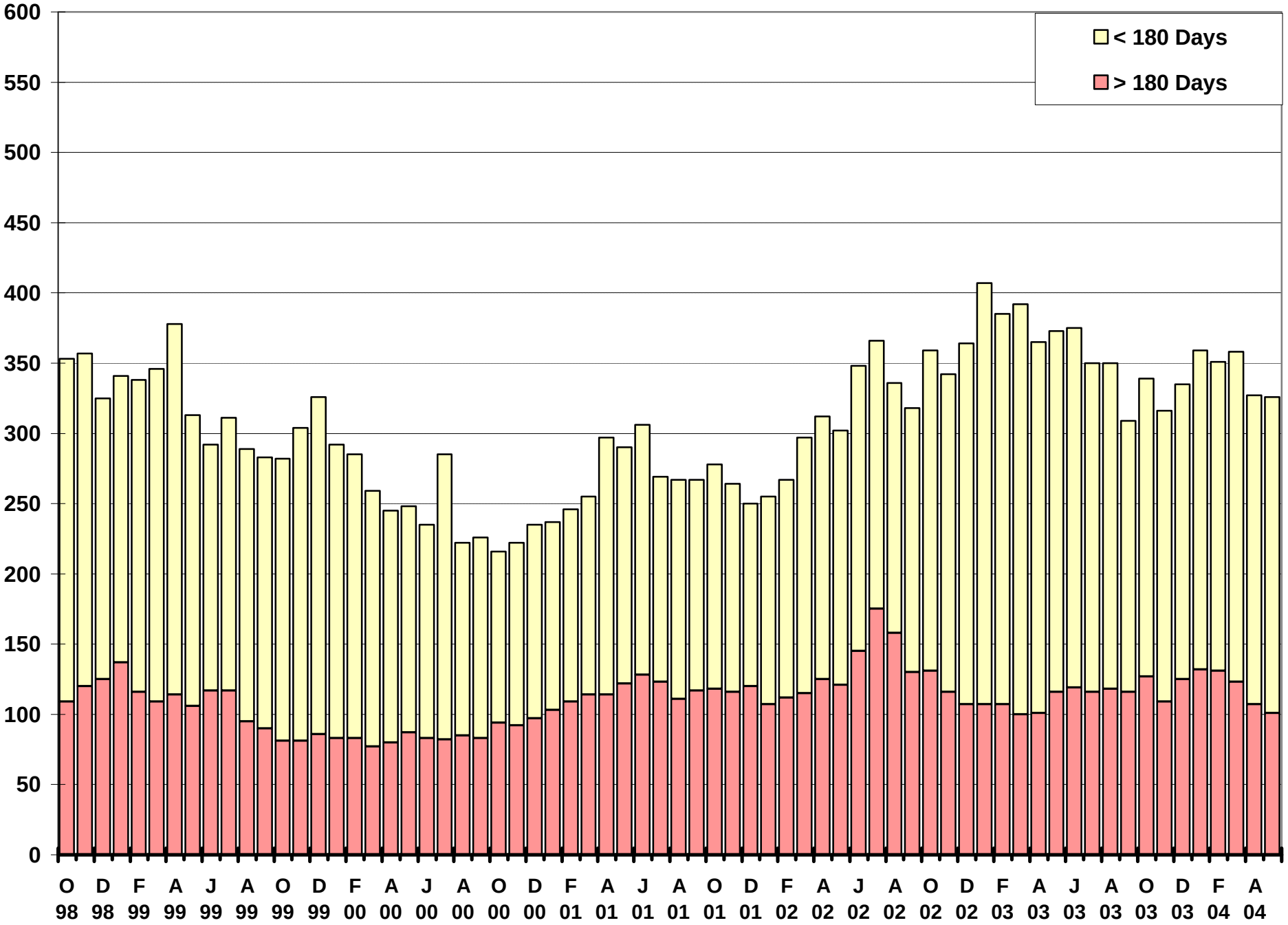


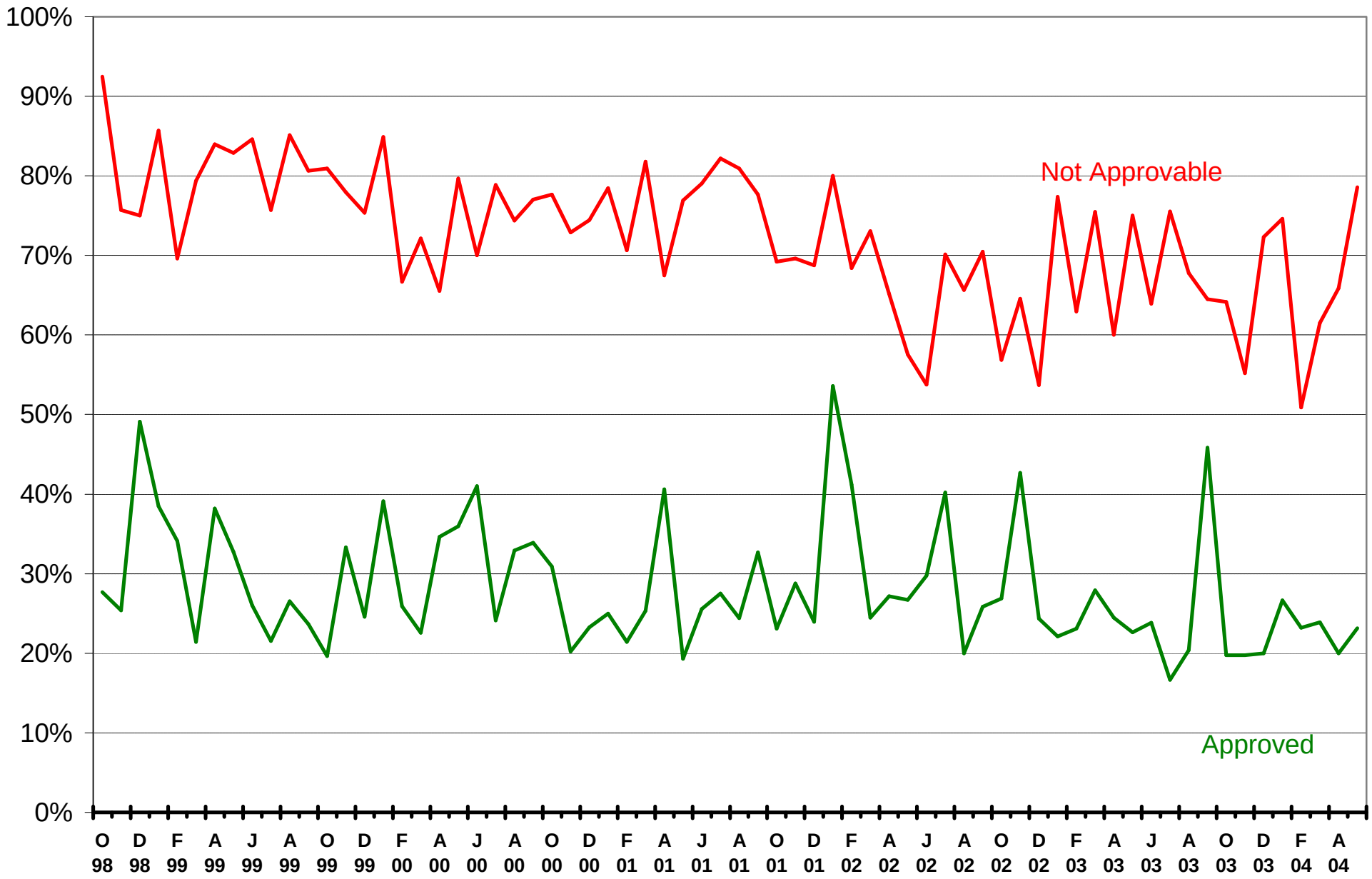
Chemistry, Manufacturing & Controls Supplements Awaiting OGD Action



Please note that abrupt changes in the level of pending supplements (e.g., the increase in November 1998) are the result of global submissions to all applications held by a single firm. Changes other than these will be explained separately.

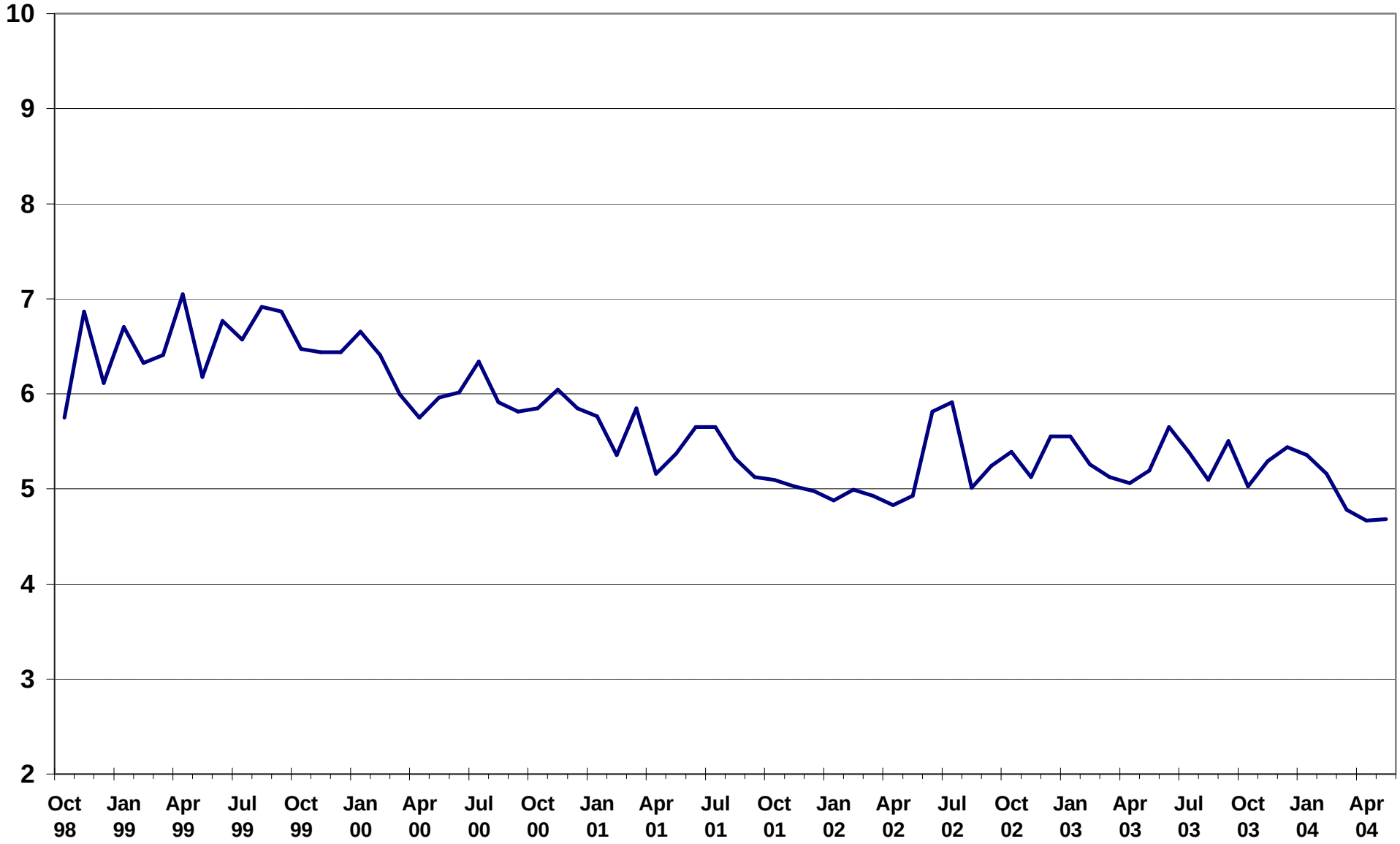
Labeling Supplements Awaiting OGD Action




ANDA Originals
Percent Approved and Not-Approvable
By Month
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
Not Approvable
Approved
O 98
D 98
F 99
A 99
J 99
A 99
O 99
D 99
F 00
A 00
J 00
A 00
O 00
D 00
F 01
A 01
J 01
A 01
O 01
D 01
F 02
A 02
J 02
A 02
O 02
D 02
F 03
A 03
J 03
A 03
O 03
D 03
F 04
A 04

Median ANDA Review Cycle (Months)

Original Applications & Major Amendments

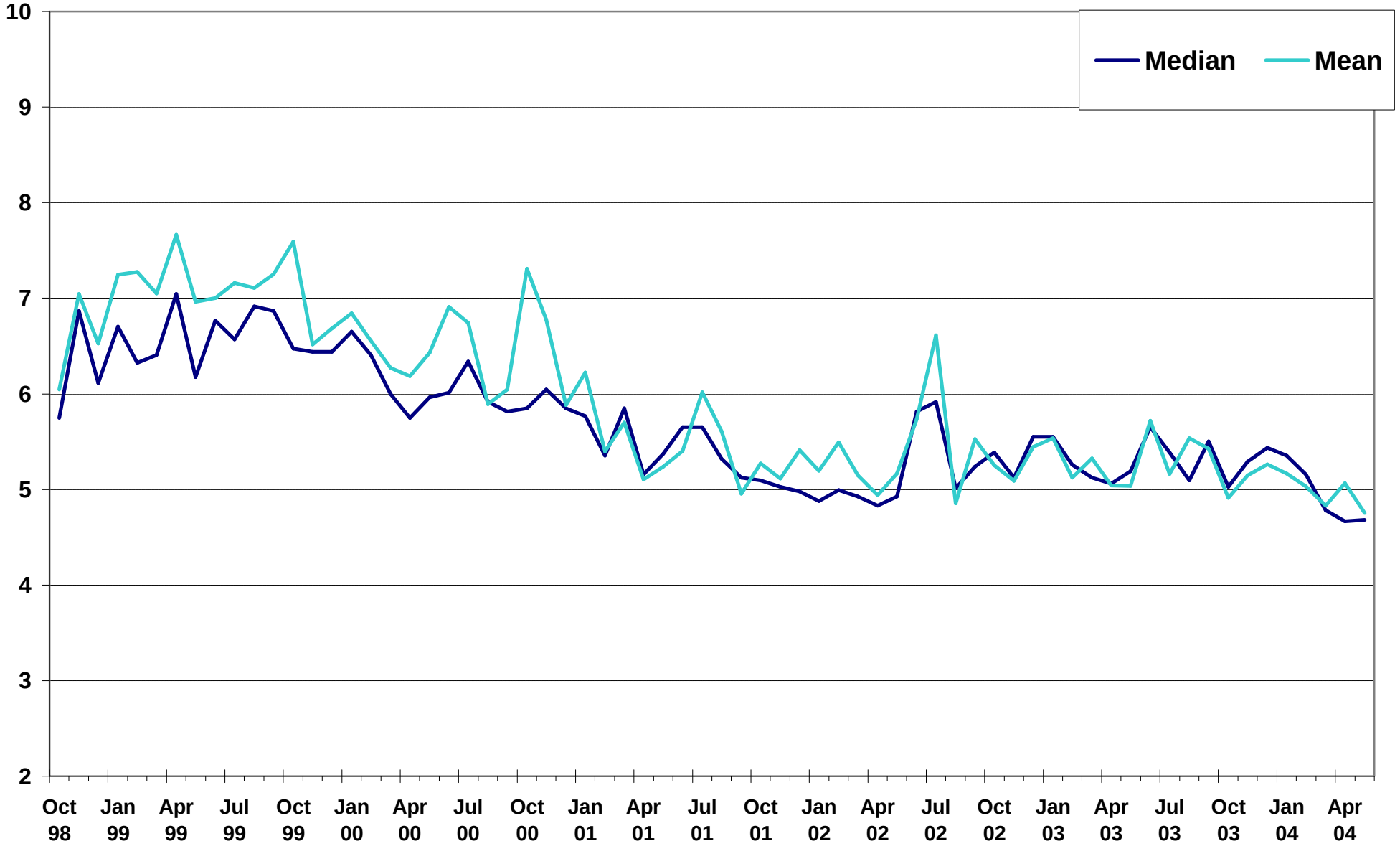


1 - Times correspond to actual applications received. The new ANDA/AADA submission policy that went into effect 1/1/91 allows certain variations in a drug product to be included in a single application.

2 - In September 1991, the OGD started implementation of the Application Integrity Policy by suspending review of applications suspected of being tainted by fraud. AIP time has therefore, been subtracted from review time after 9/91. However, before the AIP went into effect, the review of many applications suspected of containing fraudulent data were suspended. These suspensions were not recorded in the MIS and are reflected in the above chart.

Mean and Median ANDA Review Cycle (Months)

Original Applications & Major Amendments



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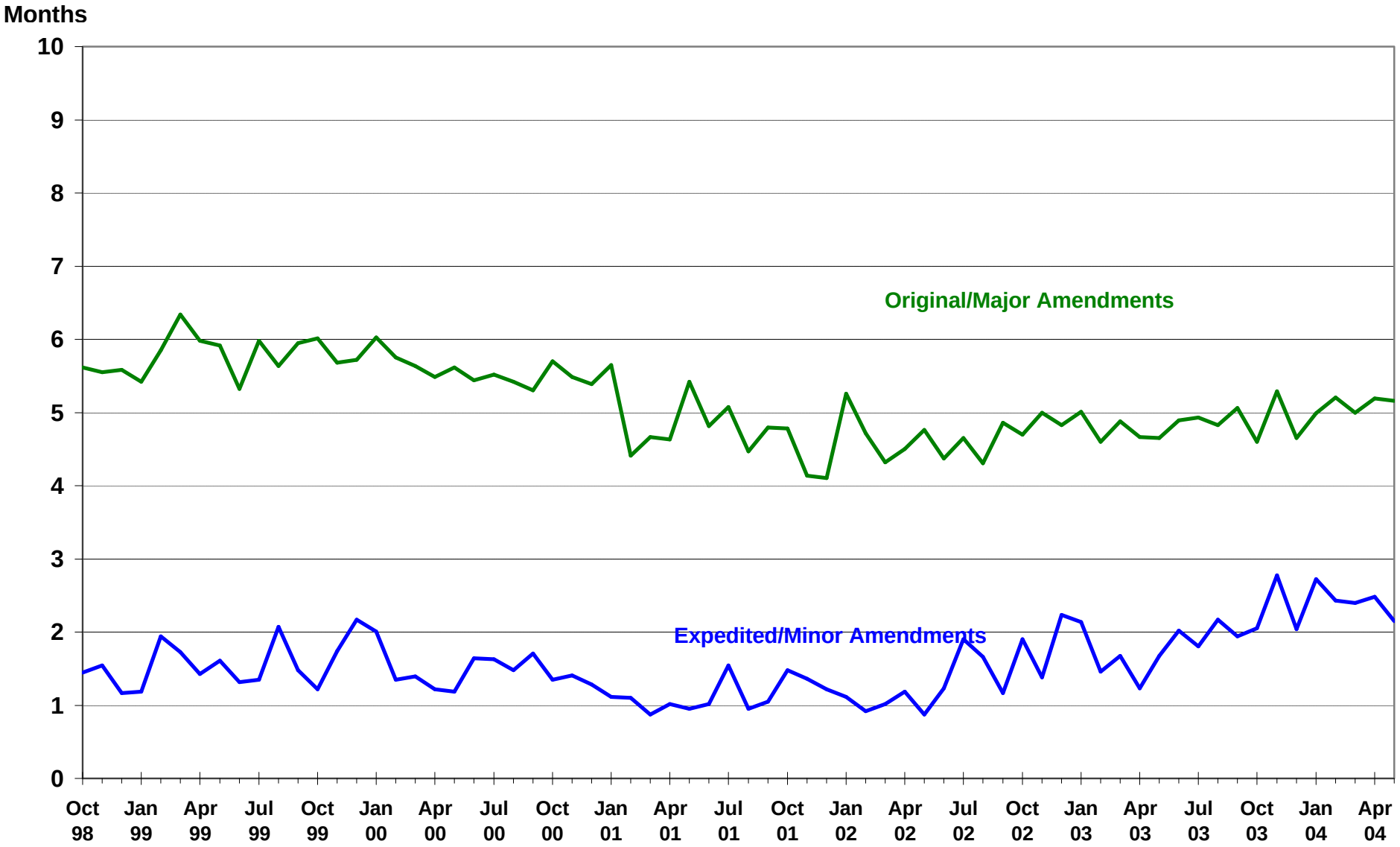
Median ANDA CMC Supplement Review Time



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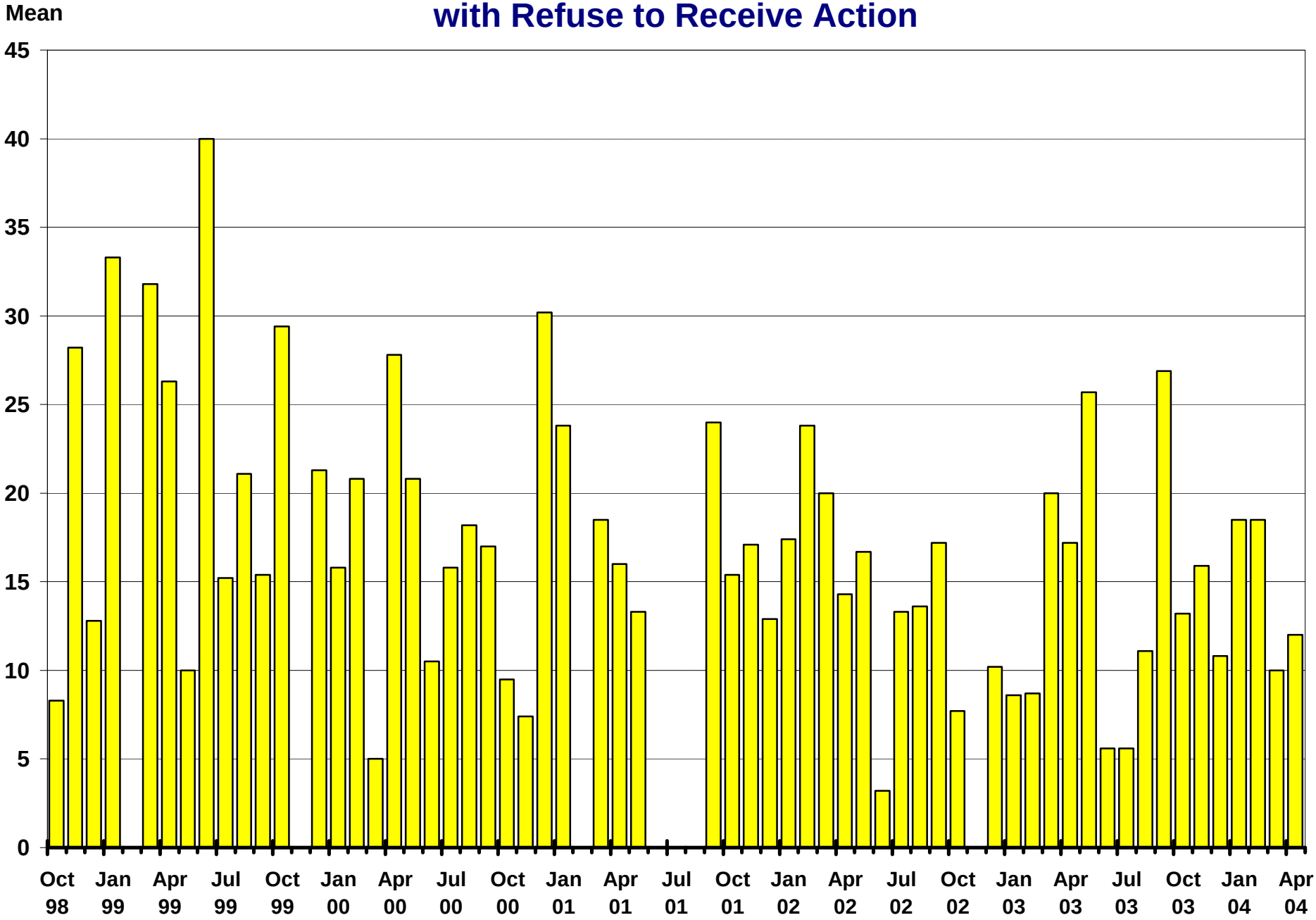
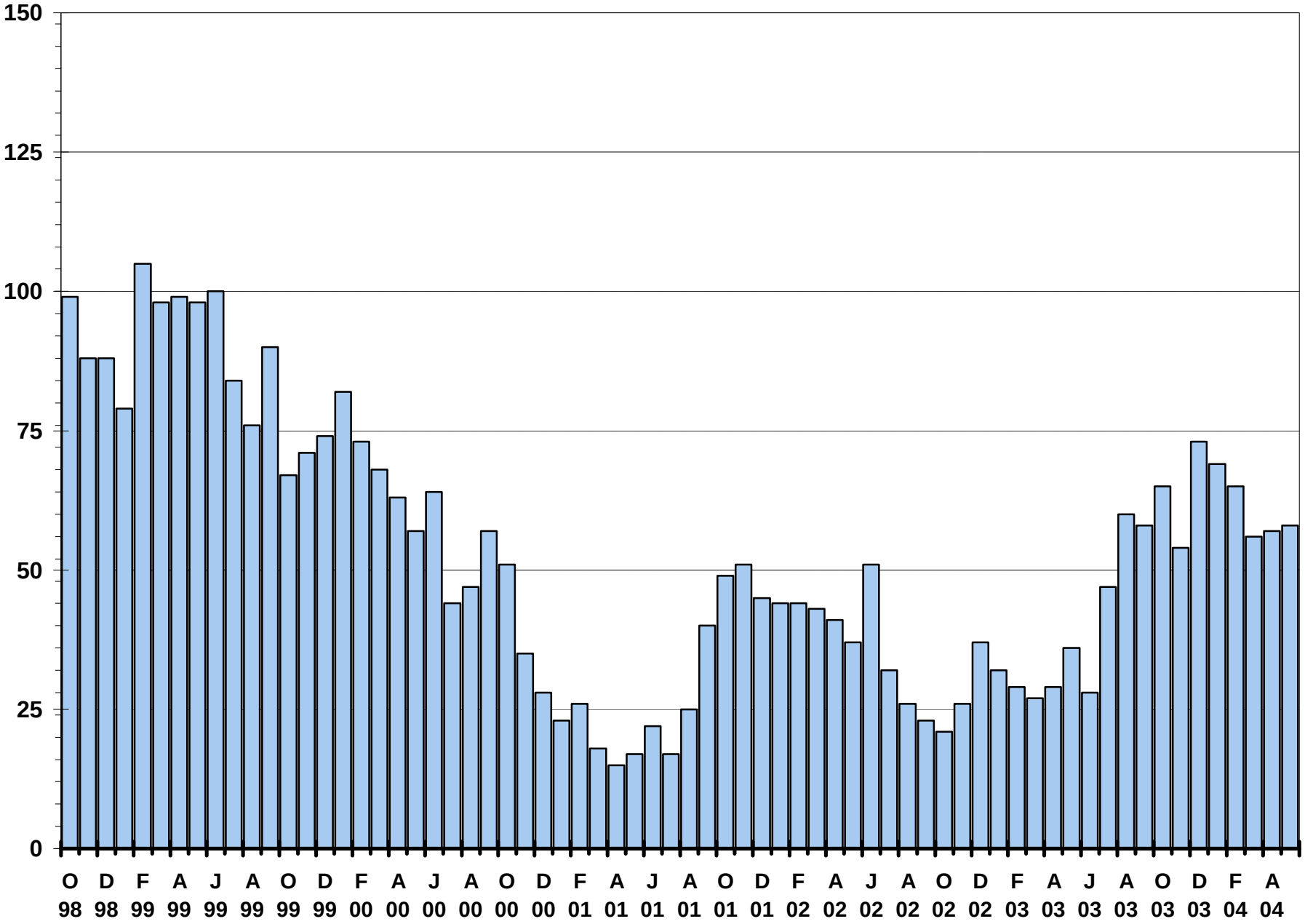
3 - Global Supplements are Collapsed

Percent of Original Submissions with Refuse to Receive Action

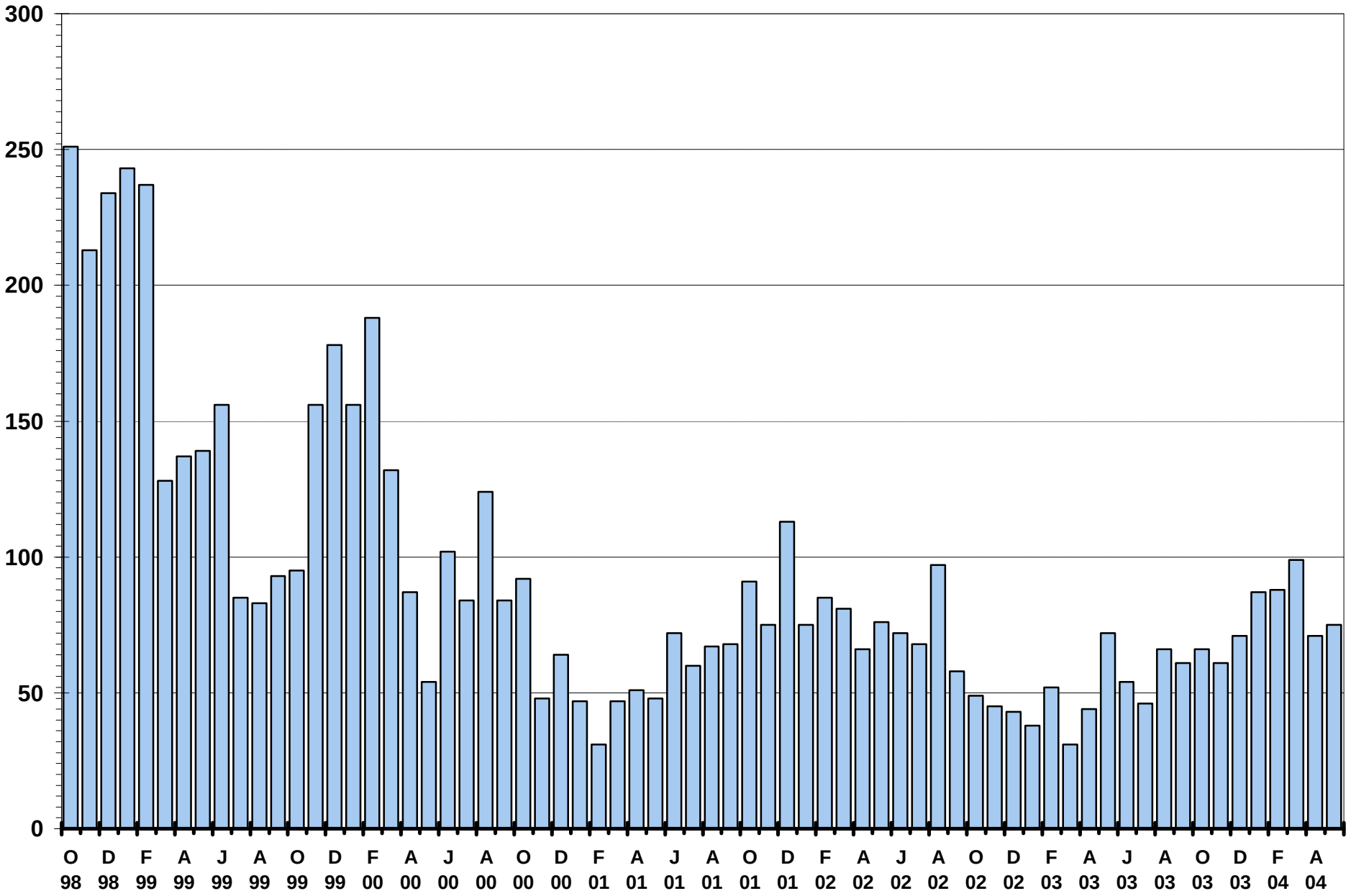


Status as of April 30, 2004. Percentages for recent months may increase due to future R/R actions

Original ANDAs Pending > 180 Days



ANDAs CMC Supplements Pending > 180 Days



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